



Substitute for form 1449A/PTO

Complete if Known

**FOURTH SUPPLEMENTAL
INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 2

Application Number	10/527,411
Filing Date	November 10, 2005 (§ 371 Date)
First Named Inventor	SHONE, Charles Clifford
Art Unit	1645
Examiner Name	Archie, Nina
Attorney Docket Number	1581.0130005/RWE

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	US10	2003/0180289 A1	09/25/2003	Foster <i>et al.</i>	
	US11	2005/0013831 A1	01/20/2005	Foster <i>et al.</i>	
	US12	2005/0244435 A1	11/03/2005	Shone <i>et al.</i>	
	US13	2005/0255093 A1	11/17/2005	Shone <i>et al.</i>	
	US14	2006/0110409 A1	05/25/2006	Shone <i>et al.</i>	
	US15	7,052,702 B1	05/30/2006	Duggan <i>et al.</i>	
	US16	2006/0121056 A1	06/08/2006	Chaddock <i>et al.</i>	
	US17	2007/0010447 A1	01/11/2007	Quinn <i>et al.</i>	
	US18	7,193,066 B1	03/20/2007	Chaddock <i>et al.</i>	
	US19	7,192,596 B2	03/20/2007	Shone <i>et al.</i>	
	US20	2007/0071764 A1	03/29/2007	Sullivan <i>et al.</i>	
	US21	7,208,466 B1	04/24/2007	Foster <i>et al.</i>	
	US22	2007/0148694 A1	06/28/2007	Shone <i>et al.</i>	
	US23	2007/0184048 A1	08/09/2007	Foster <i>et al.</i>	
	US24	2007/0184070 A1	08/09/2007	Shone <i>et al.</i>	
	US25	2007/0248626 A1	10/25/2007	Shone <i>et al.</i>	
	US26	2008/0032930 A1	02/07/2008	Steward <i>et al.</i>	
	US27	2008/0032931 A1	02/07/2008	Steward <i>et al.</i>	
	US28	2008/0032928 A1	02/07/2008	Quinn <i>et al.</i>	
	US29	2008/0038274 A1	02/14/2008	Foster <i>et al.</i>	
	US30	2008/0064092 A1	03/13/2008	Foster <i>et al.</i>	
	US31	2008/0070278 A1	03/20/2008	North <i>et al.</i>	
	US32	7,368,532 B2	05/06/2008	Shone <i>et al.</i>	
	US33	2008/0152667 A1	06/26/2008	Quinn <i>et al.</i>	
	US34	2008/0161543 A1	07/03/2008	Steward <i>et al.</i>	
	US35	2008/0187960 A1	08/07/2008	Foster <i>et al.</i>	
	US36	7,413,742 B2	08/19/2008	Donovan	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)			
	FP4	WO 2006/026780 A1	03/09/2006	Allergan, Inc.	
	FP5	WO 2006/059093 A2	06/08/2006	Health Protection Agency; Allergan, Inc.	
	FP6	WO 2006/059105 A2	06/08/2006	Health Protection Agency	
	FP7	WO 2007/138336 A2	12/06/2007	Syntaxin Limited; Allergan, Inc.	
	FP8	WO 2007/138339 A2	12/06/2007	Syntaxin Limited; Allergan, Inc.	
	FP9	WO 2008/008805 A2	01/17/2008	Allergan, Inc.	

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Equivalent of Form PTO/SB/08b (2-09)

Substitute for form 1449/PTO				Complete if Known	
FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/527,411
				Filing Date	November 10, 2005 (§ 371 Date)
				First Named Inventor	SHONE, Clifford Charles
				Art Unit	1645
				Examiner Name	Archie, Nina
Sheet	1	of	3	Attorney Docket Number	1581.0130005/RWE

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	NPL4	Atassi, M.Z., "Basic Immunological Aspects of Botulinum Toxin Therapy," <i>Movement Disorders 19</i> : S68-S84, Movement Disorder Society (2004)	
	NPL5	Blaustein, R.O., <i>et al.</i> , "The N-terminal half of the heavy chain of botulinum type A neurotoxin forms channels in planar phospholipid bilayers," <i>F.E.B.S. Letters 226</i> :115-120, Elsevier Science Publishers B.V. (1987)	
	NPL6	Bowie J.U., <i>et al.</i> , "Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions," <i>Science 247</i> :1306-1310, American Association for the Advancement of Science (1990)	
	NPL7	Brüggemann, H., <i>et al.</i> , "The genome sequence of <i>Clostridium tetani</i> , the causative agent of tetanus disease," <i>PNAS 100</i> :1316-1321, National Academy of Sciences (2003)	
	NPL8	Brunger, A.T., <i>et al.</i> , "Botulinum Neurotoxin Heavy Chain Belt as an Intramolecular Chaperone for the Light Chain," <i>PLoS Pathogens 3</i> :1191-1194 (2007)	
	NPL9	Byrne, M.P., <i>et al.</i> , "Purification, Potency, and Efficacy of the Botulinum Neurotoxin Type A Binding Domain from <i>Pichia pastoris</i> as a Recombinant Vaccine Candidate," <i>Infection and Immunity 66</i> :4817-4822, American Society for Microbiology (1998)	
	NPL10	Byrne, M.P., <i>et al.</i> , "Development of vaccines for prevention of botulism," <i>Biochimie 82</i> :955-966, Elsevier SAS (2000)	
	NPL11	Creighton, T.E., Proteins, pages 314-315, W.H. Freeman Company (1984)	
	NPL12	Creighton, T.E., Protein Structure: A Practical Approach, pages 184-186, IRL Press (1989)	
	NPL13	Eisel, U., <i>et al.</i> , "Tetanus toxin: primary structure, expression in <i>E. coli</i> , and homology with botulinum toxins," <i>The EMBO Journal 5</i> :2495-2502, IRL Press Limited (1986)	
	NPL14	Goonetilleke, A., <i>et al.</i> , "Clostridial Neurotoxins," <i>J Neurol Neurosurg Psychiatry 75</i> :iii35-iii39, BMJ Journals (2004)	
	NPL15	Hill, K.K., <i>et al.</i> , "Genetic Diversity among Botulinum Neurotoxin-Producing Clostridial Strains," <i>Journal of Bacteriology 189</i> :818-832, American Society of Microbiology (2007)	

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		Filing Date	November 10, 2005 (§ 371 Date)		
		First Named Inventor	SHONE, Clifford Charles		
		Art Unit	1645		
		Examiner Name	Archie, Nina		
Sheet	2	of	3	Attorney Docket Number	1581.0130005/RWE

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	NPL16	Kumar, V., <i>et al.</i> , "Amino Acid Variations at a Single Residue in an Autoimmune Peptide Profoundly Affect its Properties: T-Cell Activation, Major Histocompatibility Complex Binding, and Ability to Block Experimental Allergic Encephalomyelitis," <i>PNAS</i> 87:1337-1341, National Academy of Sciences (1990)	
	NPL17	Nosoh, Y., Protein Stability and Stabilization Through Protein Engineering, pages 197-217, Prentice Hall (1991)	
	NPL18	Abstract of Park, J-B., <i>et al.</i> , "Progress toward development of an inhalation vaccine against botulinum toxin," <i>Expert Review of Vaccines</i> 3:477-487, Expert Reviews Ltd. (2004)	
	NPL19	Sebahia, M., <i>et al.</i> , "Genome sequence of a proteolytic (Group I) <i>Clostridium botulinum</i> strain Hall A and comparative analysis of the clostridial genomes," <i>Genome Research</i> 17:1082-1092, Cold Spring Harbor Laboratory Press (2007)	
	NPL20	Shone, C.C., <i>et al.</i> , "A 50-kDa fragment from the NH ₂ -terminus of the heavy subunit of <i>Clostridium botulinum</i> type A neurotoxin forms channels in lipid vesicles," <i>Eur. J. Biochem</i> 167:175-180, F.E.B.S. (1987)	
	NPL21	Willems, A., <i>et al.</i> , "Sequence of the gene coding for the neurotoxin of <i>Clostridium botulinum</i> type A associated with infant botulism: comparison with other clostridial neurotoxins," <i>Res. Microbiol.</i> 144:547-556, Elsevier (1993)	
	NPL22	Office Action mailed March 21, 2008 in U.S. Patent Appl. No. 11/077,550 to Shone, C.C., <i>et al.</i>	
	NPL23	Amendment and Reply Under 37 C.F.R. § 1.111 filed July 21, 2008 in U.S. Patent Appl. No. 11/077,550 to Shone, C.C., <i>et al.</i>	
	NPL24	Office Action mailed October 27, 2008 in U.S. Patent Appl. No. 11/077,550 to Shone, C.C., <i>et al.</i>	
	NPL25	Reply Under 37 C.F.R. § 1.116 filed February 19, 2009 in U.S. Patent Appl. No. 11/077,550 to Shone, C.C., <i>et al.</i>	

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	NPL26	Office Action mailed March 30, 2009 in U.S. Patent Appl. No. 11/077,550 to Shone, C.C., <i>et al.</i>	
	NPL27	Office Action mailed April 6, 2009 in U.S. Patent Appl. No. 11/644,010 to Shone, C.C., <i>et al.</i>	
	NPL28	Copy of co-pending U.S. Application No. 12/399,542, inventors Shone, C.C., <i>et al.</i> , filed March 6, 2009 (NOT PUBLISHED)	
	NPL29	Copy of co-pending U.S. Application No. 12/369,341, inventors Shone, C.C., <i>et al.</i> , filed February 11, 2009 (NOT PUBLISHED)	
	NPL30	Copy of co-pending U.S. Application No. 12/174,896, inventors Shone, C.C., <i>et al.</i> , filed July 17, 2008 (NOT PUBLISHED)	

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